BLOOD CENTERS OF CALIFORNIA

October 14, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket Number 97D-0318

Dear Sir:

On August 17, 1999 the Guidance for Industry entitled, "Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products" was published in the Federal Register. The Board of the Blood Centers of California (BCC) has charged its Medical-Technical Advisory Committee (MTAC) with submitting input on the above-referenced Docket which we hope will be of assistance to the Agency as they move ahead in this area.

BCC is a consortium of 18 not-for-profit blood centers supplying approximately 1 million units of blood to patients in California every year. The MTAC comprises the Medical Directors, a number of Quality Assurance Directors, Nursing Directors and Technical Directors from each of the member blood centers. In addition, a representative of the California Department of Health Services sits on the committee and we have a formal liaison with the American Association of Blood Banks Standards Committee.

While we applaud the Agency's efforts to maintain the safest blood supply possible, we have serious concerns about the impact of the proposed regulation on blood availability in our State. There are several published estimates which indicate another 2-3% of our volunteer donor pool will be deferred per your recommendations. Our member centers are already struggling to provide safe and available blood from an ever decreasing donor pool which will be further compromised.

In addition, the donors most frequently deferred will be our older, repeat donors who are more likely to have the time and discretionary income to travel to the UK. The loss to the blood supply should not be measured in terms of the number of donors deferred but in terms of the number of donations lost. To make up the

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deficit we will have to recruit new donors who are not as familiar with donor eligibility criteria and who have not been previously screened for viral markers. As a result, we will lose much of this newly recruited blood to various donor history deferrals and tests. While this blood does not get used, it is indicative of a population with a higher prevalence of transfusion-transmissible markers with a corresponding higher risk of a false negative test. This presents a real and immediate danger to the recipients of such units while ostensibly reducing the risk of a theoretical one.

This is not a concern unique to California. In 1997 the National Blood Data Resources Center published the **Report on Blood Collection and Transfusion in the United States** in which it is shown that usage will exceed available blood and blood components by the year 2000. In addition, the GAO report on Blood availability estimated that a decrease of 1-2% from current levels would have an immediate impact on blood availability. The predicted level of deferral is greater than that.

We are concerned that the efforts necessary to recruit this new group of donors may result in a decrease in safety of the blood supply, all in an effort to prevent a risk that it purely theoretical. Consider the strategies that will be employed or are being considered:

1. The percentage of first time donors, which in California now comprise approximately 20% or less of blood donated, will increase.

2. Several groups are struggling to find ways to bring previously deferred individuals back into the donor pool, eg, hemachromatosis patients, to help remedy the shortfall. This at the same time as we are debating the role of incentives to donate in decreasing blood safety.

3. Already the United States has an insufficient blood supply; we will have to increase our usual source of imported blood from Europe where travel to, and use of bovine products from the UK, is certainly greater than in the United States.

Finally, the Committee wished to strongly recommend that the agency consider other alternatives which will not impact the adequacy of the blood supply. Following reports that nvCJD is concentrated in lymphoid tissues, the Europeans and Canadians have moved rapidly toward universal leukoreduction. This certainly

has at least as much theoretical advantage in terms of preventing transmission of CJD as the proposed UK deferral. The Committee urges you to consider mandating universal leukoreduction. At least this mechanism provides some proven benefits in addition to a theoretical benefit, as opposed to a mechanism that has no documented validity and will further stress an already marginal donor supply.

We appreciate the opportunity to comment on this issue and look forward to the agency's next version of the Guidance Document.

Sincerely,

Cherie S. Evans MD

Cherie S. Evans, M.D.
Chair
Medical Technical Advisory Committee

Federal Express

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